

CLAIMS:

1. An expandable sheath for deploying a medical device, comprising:
a first polymeric layer;
a braided layer radially outward of the first polymeric layer, the braided layer comprising a plurality of filaments braided together;
a second polymeric layer radially outward of the braided layer and bonded to the first polymeric layer such that the braided layer is encapsulated between the first and second polymeric layers;
wherein when a medical device is passed through the sheath, the diameter of the sheath expands from a first diameter to a second diameter around the medical device.
2. The expandable sheath of claim 1, wherein when a medical device is passed through the sheath, the diameter of the sheath expands from a first diameter to a second diameter around the medical device while resisting axial elongation of the sheath such that a length of the sheath remains substantially constant.
3. The expandable sheath of either of claims 1 or 2, wherein a portion of the plurality of filaments comprise an elastic coating.
4. The expandable sheath of claim 3, wherein a portion of the first polymeric layer and/or a portion of the second polymeric layer comprises an elastic coating.
5. The expandable sheath of any one of claims 1-4, wherein the braided layer comprises a self-contracting material.
6. The expandable sheath of any one of claims 1-5, wherein the first and second polymeric layers comprise a plurality of longitudinally-extending folds when the sheath is at the first diameter, the longitudinally-extending folds creating a plurality of circumferentially spaced ridges and a plurality of circumferentially spaced valleys, wherein, as a medical device is passed through the sheath, the ridges and valleys level out to allow the sheath to radially expand.

7. The expandable sheath of any one of claims 1-6, wherein the filaments of the braided layer are movable between the first and second polymeric layers such that the braided layer is configured to radially expand as a medical device is passed through the sheath while the length of the sheath remains substantially constant.

8. The expandable sheath of any one of claims 1-7, wherein the filaments of the braided layer are resiliently buckled when the sheath is at the first diameter, and the first and second polymeric layers are attached to each other at a plurality of open spaces between the filaments of the braided layer.

9. The expandable sheath of any one of claims 1-8, further comprising an outer cover formed of a heat shrink material and extending over at least a longitudinal portion of the first polymeric layer, the braided layer, and the second polymeric layer, the outer cover comprising one or more longitudinally extending slits, weakened portions, or scorelines.

10. The expandable sheath of any one of claims 1-9, further comprising at least one cushioning layer positioned between the braided layer and an adjacent polymeric layer, wherein the cushioning layer dissipates radial forces acting between filaments of the braided layer and the adjacent polymeric layer.

11. The expandable sheath of claim 10, wherein the cushioning layer has a thickness of from 80 microns to 1000 microns.

12. The expandable sheath of either of claims 10 or 11, further comprising a first cushioning layer positioned between the braided layer and the first polymeric layer, and a second cushioning layer positioned between the braided layer and the second polymeric layer.

13. The expandable sheath of any one of claims 10-12, wherein the cushioning layer comprises a porous interior region.

14. The expandable sheath of claim 13, wherein the cushioning layer further comprises a sealed surface positioned between the porous interior region and the adjacent polymeric layer, wherein the sealed surface has a higher melting point than the adjacent polymeric layer and is thinner than the porous interior region of the cushioning layer.

15. The expandable sheath of claim 14, wherein the sealed surface is a sealing layer attached to the cushioning layer.

16. The expandable sheath of either of claims 14 or 15, wherein the sealed surface is a surface of the cushioning layer and the sealed surface is continuous with and formed of the same material as the porous interior region of the cushioning layer.

17. An expandable sheath for deploying a medical device, comprising:
a braided layer comprising a plurality of filaments braided together;
a first expandable sealing layer adhered to a portion of the filaments of the braided layer, the sealing layer being impermeable to blood flow;
wherein when a medical device is passed through the sheath, the diameter of the sheath expands from a first diameter to a second diameter around the medical device.

18. The expandable sheath of claim 17, further comprising a second expandable sealing layer adhered to a portion of the filaments of the braided layer, the second expandable sealing layer positioned on the opposite side of the braided layer as the first expandable sealing layer.

19. The expandable sheath of either of claims 17 or 18, wherein at least a portion of the plurality of filaments comprise a sealing coating.

20. The expandable sheath of any one of claims 17-19, wherein the braided layer comprises a self-contracting material.

21. The expandable sheath of claim 20, wherein the expandable sealing layer varies in thickness according to the longitudinal position of the sheath.

22. A method of making an expandable sheath, the method comprising:
placing a braided layer radially outward of a first polymeric layer situated on a mandrel, the braided layer comprising a plurality of filaments braided together, the mandrel having a first diameter;
applying a second polymeric layer radially outward of the braided layer;
applying heat and pressure to the first polymeric layer, the braided layer, and the second polymeric layer such that the first and second polymeric layers bond to each other and encapsulate the braided layer to form an expandable sheath; and
removing the expandable sheath from the mandrel to allow the expandable sheath to at least partially radially collapse to a second diameter that is less than the first diameter.
23. The method of claim 22, further comprising applying an elastic coating to a portion of the plurality of filaments.
24. The method of claim 23, further comprising applying an elastic coating to a portion of the first polymeric layer and/or a portion of the second polymeric layer.
25. The method of any one of claims 22-24, further comprising shape-setting the braided layer to a contracted diameter prior to placing the braided layer radially outward of the first polymeric layer.
26. The method of any one of claims 22-25, wherein applying heat and pressure further comprises placing the mandrel in a vessel containing a thermally-expandable material, heating the thermally-expandable material in the vessel, and applying a radial pressure of 100 MPa or more to the mandrel via the thermally-expandable material.
27. The method of any one of claims 22-26, wherein applying heat and pressure further comprises applying a heat shrink tubing layer over the second polymeric layer and applying heat to the heat shrink tubing layer.

28. The method of any one of claims 22-27, further comprising resiliently buckling the filaments of the braided layer as the sheath is radially collapsed to the second diameter.

29. The method of any one of claims 22-28, further comprising sealing a surface of a cushioning layer, and applying the cushioning layer such that the sealed surface contacts the first polymeric layer or the second polymeric layer.

30. The method of any one of claims 22-29, further comprising crimping the expandable sheath to a third diameter, the third diameter being smaller than the first diameter and the second diameter.

31. The sheath of any one of claims 1-21, further comprising a distal end portion having a predetermined length and comprising two or more layers.

32. The sheath of claim 31, wherein the distal end portion extends distally beyond a longitudinal portion of the sheath comprising the braided layer.

33. The sheath of any one of claims 31-32, wherein the distal end portion comprises an inner polymeric layer and an outer polymeric layer.

34. The sheath of any one of claims 31-33, wherein the distal end portion further comprises an external covering.

35. The sheath of any one of claims 32-34, wherein a portion of the distal end portion comprises a portion of a distal end of the braided layer.

36. The sheath of claim 35, wherein the portion of the distal end of the braided layer comprises loops.

37. The sheath of any one of claims 34-36, wherein the external covering has a melting temperature lower than a melting temperature of the inner polymeric layer.

38. The sheath of any one of claims 34-37, wherein the external covering has a melting temperature lower than a melting temperature of the outer polymeric layer.

39. The sheath of any one of claims 34-38, wherein the external covering comprises a low density polyethylene.

40. The sheath of any one of claims 34-39, wherein a portion of the sheath proximal to the distal end portion of the sheath does not comprise the external covering.

41. The sheath of any one of claims 34-40, wherein a portion of the sheath extending from a proximal end of the sheath to a portion of the sheath proximal to the distal end portion of the sheath does not comprise the external covering.

42. The sheath of any one of claims 31-41, wherein the sheath comprises at least one attachment region between the distal end portion and a portion of the sheath proximal to the distal end.

43. The sheath of claim 42, wherein the attachment region is a circumferential attachment region.

44. The sheath of claim 42, wherein the attachment region comprises a plurality of circumferentially spaced attachment regions.

45. The sheath of any one of claims 33-44, wherein the distal end portion of the sheath comprises a first plurality of folds present in the inner layer.

46. The sheath of any one of claims 33-45, wherein the distal end portion of the sheath comprises a second plurality of folds present in the outer layer.

47. The sheath of any one of claims 34-46, wherein the distal end portion of the sheath comprises a third plurality of folds present in the external covering.

48. The sheath of claim 47, wherein folds in the third plurality of folds present in the external covering are at least partially attached to each other.

49. A method of forming a tip of a sheath comprising
pre-crimping a distal end portion of the sheath of any one of claims 1-21 to a first diameter, wherein the distal end portion extends distally beyond a longitudinal portion of the sheath comprising the braided layer and comprises an inner polymeric layer and an outer polymeric layer; wherein the inner polymeric layer and the outer layer exhibit a first melting temperature;

covering the pre-crimped distal end portion with an external covering; wherein the external covering exhibits a second melting temperature, wherein the second melting temperature is lower than the first melting temperature;

heating at least a portion of the pre-crimped distal end portion covered with the external covering to a first temperature, wherein the first temperature is equal or greater than the first melting temperature, thereby forming at least one attachment region between the external cover and the inner and outer polymeric layers;

inserting a mandrel into a lumen of at least a portion of the distal end portion and further crimping the at least a portion of the distal end portion to a second diameter; and

heating the at least a portion of the distal end portion to a second temperature, wherein the second temperature is equal or greater than the second melting temperature.

50. The method of claim 49, wherein the second temperature is lower than the first melting temperature.

51. The method of claim 49 or 50, wherein the second diameter is smaller than the first diameter.

52. The method of any one of claims 49-51, wherein the step of crimping forms a plurality of folds along the external covering.

53. The method of any one of claims 49-52, wherein the inner polymeric layer and outer polymeric layer comprise a plurality of folds.

54. The method of claim 53, wherein the plurality of folds in the inner polymeric layer and the outer polymeric layer are formed at the pre-crimping step.

55. The method of claim 53, wherein the plurality of folds in the inner polymeric layer and the outer polymeric layer are formed at the crimping step.

56. The method of any one of claims 52-55, wherein the step of heating to the second temperature forms an attachment between at least a portion of the plurality of folds in the external covering to each other.

57. The method of any one of claims 49-56, further comprising applying a heat-shrink material to at least a portion of the crimped distal end portion.

58. The method of claim 57, wherein the step of applying the heat-shrink material is performed prior to the step of heating to the second temperature.

59. The method of claim 57, wherein the step of applying the heat-shrink material is performed during the step of heating to the second temperature.

60. The method of claim 57, wherein the step of applying the heat-shrink material is performed after to the step of heating to the second temperature.

61. The method of any one of claims 57-60 further comprising removing the heat-shrink material after the attachment between at least a portion of the plurality of folds in the external covering to each other is formed.

62. The method of any one of claims 54-61, wherein the heat-shrink material is a tube or a tape.